**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

1.-12. (cancelled)

~~13~~. (currently amended) A method for treating a bacterial infection in a patient, the method comprising:

administering to the patient in need thereof a therapeutically effective amount of a composition in solid form comprising amoxicillin and potassium clavulanate and comprising a first release phase and a second release phase;

the first release phase comprising potassium clavulanate and a first portion of the amoxicillin;

the second release phase comprising a second portion of amoxicillin, which is a pharmaceutically acceptable soluble salt of amoxicillin, and at least one pharmaceutically acceptable organic acid which are admixed in intimate contact at a ratio of from 20:1 to 1:2 ~~(amoxicillin free acid equivalent to organic acid equivalent)~~.

14.-17. (cancelled)

~~18~~. (currently amended) A method according to claim ~~1~~-13 in which the bacterial infection is caused by at least one of the organisms *S. pneumoniae*, *H. influenzae*, and *M. catarrhalis*.

19.-68. (cancelled)

~~69~~. (previously presented) A method according to claim ~~18~~ wherein the *S. pneumoniae* are Drug Resistant *S. pneumoniae* and Penicillin Resistant *S. pneumoniae* organisms.

~~70~~. (previously presented) A method according to claim ~~13~~ wherein the amount of amoxicillin in the first release phase is released upon exposure to an aqueous environment.

5 11. (currently amended) A method according to claim 1 3 wherein the ratio of the pharmaceutically acceptable soluble salt of amoxicillin ~~free acid equivalent~~ to the at least one pharmaceutically acceptable organic acid ~~equivalent~~ in the second release phase is from about 2:1 to about 1:1.2.

6 12. (currently amended) A method according to claim 1 3 wherein the ratio of the amoxicillin ~~(amoxicillin free acid equivalent)~~ in the first release phase to the amoxicillin ~~(amoxicillin free acid equivalent)~~ in the second release phase is from about 3:1 to about 1:3.

7 13. (currently amended) A method according to claim 1 3 wherein the ratio of the amoxicillin ~~(amoxicillin free acid equivalent)~~ in the first release phase to the amoxicillin ~~(amoxicillin free acid equivalent)~~ in the second release phase is from about 2:1 to about 2:3.

4 14. (currently amended) A method according to claim 5 11 wherein the ratio of the amoxicillin ~~(amoxicillin free acid equivalent)~~ in the first release phase to the amoxicillin ~~(amoxicillin free acid equivalent)~~ in the second release phase is from about 2:1 to about 2:3.

C1 cont.

9 15. (currently amended) A method according to claim 1 3 wherein the ratio of the amoxicillin ~~(amoxicillin free acid equivalent)~~ in the first release phase to the amoxicillin ~~(amoxicillin free acid equivalent)~~ in the second release phase is from about 3:2 to about 1:1.

10 16. (currently amended) A method according to claim 5 11 wherein the ratio of the amoxicillin ~~(amoxicillin free acid equivalent)~~ in the first release phase to the amoxicillin ~~(amoxicillin free acid equivalent)~~ in the second release phase is from about 3:2 to about 1:1.

11 17. (currently amended) A method according to claim 1 3 wherein the ratio of the amoxicillin ~~(amoxicillin free acid equivalent)~~ in the first release phase to the amoxicillin ~~(amoxicillin free acid equivalent)~~ in the second release phase is about 9:7.

12 18. (previously presented) A method according to claim 1 3 wherein the at least one pharmaceutically acceptable organic acid is selected from pharmaceutically acceptable monocarboxylic and polycarboxylic acids having from 2 to 25 carbon atoms, pharmaceutically acceptable monocyclic aryl and polycyclic aryl acids, and pharmaceutically acceptable monohydrogen and dihydrogen metal salts of any of the foregoing multi-valent acids.



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79. (previously presented) The method according to claim 13 wherein the at least one pharmaceutically acceptable organic acid is selected from pharmaceutically acceptable monocarboxylic and polycarboxylic acids having from 2 to 10 carbon atoms and an acidic salt of any of the foregoing.

80. (previously presented) The method according to claim 71 wherein the at least one pharmaceutically acceptable organic acid is selected from pharmaceutically acceptable monocarboxylic and polycarboxylic acids having from 2 to 10 carbon atoms and an acidic salt of any of the foregoing.

81. (previously presented) The method according to claim 75 wherein the at least one pharmaceutically acceptable organic acid is selected from pharmaceutically acceptable monocarboxylic and polycarboxylic acids having from 2 to 10 carbon atoms and an acidic salt of any of the foregoing.

82. (previously presented) A method according to claim 13 wherein the at least one pharmaceutically acceptable organic acid is selected from $C_{(2-10)}$ alkyl- and $C_{(2-10)}$ alkenyl-carboxylic acids having one, two, or three carboxylic acid groups, and optionally at least one hydroxy substituent, and optionally at least one -CO group in the carbon chain and an acidic salt of any of the foregoing.

83. (currently amended) A method according to claim 13 wherein the at least one pharmaceutically acceptable organic acid is selected from malonic acid, succinic acid, fumaric acid, maleic acid, adipic acid, lactic acid, levulinic acid, sorbic acid, tartaric acid, ~~maleic~~ malic acid, ascorbic acid, citric acid, and an acidic salt of any of the foregoing.

84. (currently amended) A method according to claim 71 wherein the at least one pharmaceutically acceptable organic acid is selected from malonic acid, succinic acid, fumaric acid, maleic acid, adipic acid, lactic acid, levulinic acid, sorbic acid, tartaric acid, ~~maleic~~ malic acid, ascorbic acid, citric acid, and an acidic salt of any of the foregoing.

19 ~~85~~. (currently amended) A method according to claim 9 ~~75~~ wherein the at least one pharmaceutically acceptable organic acid is selected from malonic acid, succinic acid, fumaric acid, maleic acid, adipic acid, lactic acid, levulinic acid, sorbic acid, tartaric acid, ~~maleic~~ malic acid, ascorbic acid, citric acid, and an acidic salt of any of the foregoing.

20 ~~86~~. (previously presented) A method according to claim 1 ~~13~~ wherein the at least one pharmaceutically acceptable organic acid is citric acid.

21 ~~87~~. (previously presented) A method according to claim 5 ~~71~~ wherein the at least one pharmaceutically acceptable organic acid is citric acid.

22 ~~88~~. (previously presented) A method according to claim 9 ~~75~~ wherein the at least one pharmaceutically acceptable organic acid is citric acid.

23 ~~89~~. (previously presented) A method according to claim 22 ~~88~~ wherein the citric acid is citric acid anhydrous.

C1 cont. 24 ~~90~~. (previously presented) A method according to claim 1 ~~13~~ wherein the pharmaceutically acceptable soluble salt of amoxicillin is sodium amoxicillin.

25 ~~91~~. (previously presented) A method according to claim 5 ~~71~~ wherein the pharmaceutically acceptable soluble salt of amoxicillin is sodium amoxicillin.

26 ~~92~~. (previously presented) A method according to claim 9 ~~75~~ wherein the pharmaceutically acceptable soluble salt of amoxicillin is sodium amoxicillin.

27 ~~93~~. (previously presented) A method according to claim 19 ~~85~~ wherein the pharmaceutically acceptable soluble salt of amoxicillin is sodium amoxicillin.

28 ~~94~~. (previously presented) A method according to claim 22 ~~88~~ wherein the pharmaceutically acceptable soluble salt of amoxicillin is sodium amoxicillin.

29 ~~95~~. (previously presented) A method according to claim 1 ~~13~~ wherein the pharmaceutically acceptable soluble salt of amoxicillin is crystallized sodium amoxicillin.



C

30 96. (previously presented) A method according to claim 22 88 wherein the pharmaceutically acceptable soluble salt of amoxicillin is crystallized sodium amoxicillin.

31 97. (currently amended) A method according to claim 1 13 wherein the ratio of the amount of amoxicillin in the composition to the amount of potassium clavulanate ~~(amoxicillin free acid equivalent to clavulanic acid equivalent)~~ is from about 2:1 to about 20:1.

32 98. (currently amended) A method according to claim 1 13 wherein the ratio of the amount of amoxicillin in the composition to the amount of potassium clavulanate ~~(amoxicillin free acid equivalent to clavulanic acid equivalent)~~ is from about 12:1 to about 20:1.

33 99. (currently amended) A method according to claim 1 13 wherein the ratio of the amount of amoxicillin in the composition to the amount of potassium clavulanate ~~(amoxicillin free acid equivalent to clavulanic acid equivalent)~~ is from about 14:1 to about 16:1.

34 100. (currently amended) A method according to claim 5 71 wherein the ratio of the amount of amoxicillin in the composition to the amount of potassium clavulanate ~~(amoxicillin free acid equivalent to clavulanic acid equivalent)~~ is from about 14:1 to about 16:1.

C1 cont.

35 101. (currently amended) A method according to claim 9 75 wherein the ratio of the amount of amoxicillin in the composition to the amount of potassium clavulanate ~~(amoxicillin free acid equivalent to clavulanic acid equivalent)~~ is from about 14:1 to about 16:1.

36 102. (currently amended) A method according to claim 22 88 wherein the ratio of the amount of amoxicillin in the composition to the amount of potassium clavulanate ~~(amoxicillin free acid equivalent to clavulanic acid equivalent)~~ is from about 14:1 to about 16:1.

37 103. (previously presented) A method according to claim 31 97 wherein the pharmaceutically acceptable soluble salt of amoxicillin is crystallized sodium amoxicillin and the at least one pharmaceutically acceptable organic acid is citric acid anhydrous.

38 104. (previously presented) A method according to claim 1 13 wherein all of the potassium clavulanate of the composition is present in the first release phase.



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39 105. (previously presented) A method according to claim 84 wherein all of the potassium clavulanate of the composition is present in the first release phase.

40 106. (previously presented) A method according to claim 94 wherein all of the potassium clavulanate of the composition is present in the first release phase.

41 107. (previously presented) A method according to claim 13 wherein the first release phase comprises at least one pharmaceutically acceptable soluble salt of amoxicillin, amoxicillin trihydrate, or a mixture thereof.

42 108. (previously presented) A method according to claim 105 wherein the first release phase comprises at least one pharmaceutically acceptable soluble salt of amoxicillin, amoxicillin trihydrate, or a mixture thereof.

43 109. (currently amended) A method according to claim 13 wherein the amount of amoxicillin ~~(amoxicillin free acid equivalent)~~ in the composition is from about 700 mg to about 2600 mg.

C 1 Cont.

44 110. (currently amended) A method according to claim 99 wherein the amount of amoxicillin ~~(amoxicillin free acid equivalent)~~ in the composition is from about 700 mg to about 2600 mg.

45 111. (currently amended) A method according to claim 13 wherein the amount of amoxicillin ~~(amoxicillin free acid equivalent)~~ in the composition is from about 700 mg to about 1300 mg.

46 112. (currently amended) A method according to claim 99 wherein the amount of amoxicillin ~~(amoxicillin free acid equivalent)~~ in the composition is from about 700 mg to about 1300 mg.

47 113. (currently amended) A method according to claim 106 wherein the amount of amoxicillin ~~(amoxicillin free acid equivalent)~~ in the composition is from about 700 mg to about 1300 mg.

48 114. (currently amended) A method according to claim 13 wherein the amount of amoxicillin ~~(amoxicillin free acid equivalent)~~ in the composition is from about 950 mg to about 1300 mg.



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49 ~~115~~. (currently amended) A method according to claim 36 ~~102~~ wherein the amount of amoxicillin ~~(amoxicillin free acid equivalent)~~ in the composition is from about 950 mg to about 1300 mg.

50 ~~116~~. (currently amended) A method according to claim 1 ~~13~~ wherein the amount of amoxicillin ~~(amoxicillin free acid equivalent)~~ in the composition is from about 1400 mg to about 2600 mg.

51 ~~117~~. (currently amended) A method according to claim 36 ~~102~~ wherein the amount of amoxicillin ~~(amoxicillin free acid equivalent)~~ in the composition is from about 1400 mg to about 2600 mg.

52 ~~118~~. (currently amended) A method according to claim 1 ~~13~~ wherein the amount of amoxicillin ~~(amoxicillin free acid equivalent)~~ in the composition is from about 1900 mg to about 2600 mg.

53 ~~119~~. (currently amended) A method according to claim 40 ~~106~~ wherein the amount of amoxicillin ~~(amoxicillin free acid equivalent)~~ in the composition is from about 1900 mg to about 2600 mg.

54 ~~120~~. (currently amended) A method according to claim 1 ~~13~~ wherein the amount of amoxicillin ~~(amoxicillin free acid equivalent)~~ in the composition is about 1000 mg or about 2000 mg.

C 1 cont.

55 ~~121~~. (currently amended) A method according to claim 42 ~~108~~ wherein the amount of amoxicillin ~~(amoxicillin free acid equivalent)~~ in the composition is about 1000 mg or about 2000 mg.

56 ~~122~~. (currently amended) A method according to claim 1 ~~13~~ wherein the amount of amoxicillin ~~(amoxicillin free acid equivalent)~~ administered to the patient is about 2000 mg.

57 ~~123~~. (currently amended) A method according to claim 1 ~~13~~ wherein the amount of amoxicillin ~~(amoxicillin free acid equivalent)~~ in the second release phase is from about 60% to about 80% by weight of the second release phase.

58 ~~124~~. (currently amended) A method according to claim 39 ~~105~~ wherein the amount of amoxicillin ~~(amoxicillin free acid equivalent)~~ in the second release phase is from about 60% to about 80% by weight of the second release phase.



C

59 125. (currently amended) A method according to claim 53 ~~119~~ wherein the amount of amoxicillin ~~(amoxicillin free acid equivalent)~~ in the second release phase is from about 60% to about 80% by weight of the second release phase.

60 126. (currently amended) A method according to claim 47 ~~113~~ wherein the amount of amoxicillin ~~(amoxicillin free acid equivalent)~~ in the second release phase is from about 60% to about 80% by weight of the second release phase.

61 127. (currently amended) A method according to claim 1 ~~13~~ wherein the amount of amoxicillin ~~(amoxicillin free acid equivalent)~~ in the first release phase is 563 mg +/- 5% and the amount of amoxicillin in the second release phase is 438 mg +/- 5%.

62 128. (currently amended) A method according to claim 22 ~~88~~ wherein the amount of amoxicillin ~~(amoxicillin free acid equivalent)~~ in the first release phase is 563 mg +/- 5% and the amount of amoxicillin in the second release phase is 438 mg +/- 5%.

63 129. (currently amended) A method according to claim 37 ~~103~~ wherein the amount of amoxicillin ~~(amoxicillin free acid equivalent)~~ in the first release phase is 563 mg +/- 5% and the amount of amoxicillin in the second release phase is 438 mg +/- 5%.

C 1 cont.

64 130. (currently amended) A method according to claim 40 ~~106~~ wherein the amount of amoxicillin ~~(amoxicillin free acid equivalent)~~ in the first release phase is 563 mg +/- 5% and the amount of amoxicillin in the second release phase is 438 mg +/- 5%.

65 131. (previously presented) A method according to claim 1 ~~13~~ wherein the composition is divided into multiple dosage units.

66 132. (previously presented) A method according to claim 44 ~~110~~ wherein the composition is divided into multiple dosage units.

67 133. (previously presented) A method according to claim 50 ~~116~~ wherein the composition is divided into multiple dosage units.



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68 65
134. (previously presented) A method according to claim 131 wherein the amoxicillin is present in at least two of the multiple dosage units.

69 44
135. (previously presented) A method according to claim 110 wherein the amoxicillin is present in at least two of the multiple dosage units.

70 51
136. (previously presented) A method according to claim 117 wherein the amoxicillin is present in at least two of the multiple dosage units.

71 68
137. (previously presented) A method according to claim 134 wherein the first release phase is in at least one dosage unit and the second release phase is in at least one other dosage unit.

72 40
138. (previously presented) A method according to claim 106 wherein the first release phase is in at least one dosage unit and the second release phase is in at least one other dosage unit.

73 51
139. (previously presented) A method according to claim 117 wherein the first release phase is in at least one dosage unit and the second release phase is in at least one other dosage unit.

C1 cont. 74 59
140. (previously presented) A method according to claim 125 wherein the first release phase is in at least one dosage unit and the second release phase is in at least one other dosage unit.

75 1
141. (previously presented) A method according to claim 13 wherein the composition is in the form of a compressed tablet.

76 75
142. (previously presented) A method according to claim 141 wherein the composition is in the form of a monolith tablet.

77 8
143. (previously presented) A method according to claim 74 wherein the composition is in the form of a compressed tablet.

78 19
144. (previously presented) A method according to claim 85 wherein the composition is in the form of a compressed tablet.



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79 145. (previously presented) A method according to claim 27 wherein the composition is in the form of a compressed tablet.

80 146. (previously presented) A method according to claim 79 wherein the composition is in the form of a monolith tablet.

81 147. (previously presented) A method according to claim 37 wherein the composition is in the form of a compressed tablet.

82 148. (previously presented) A method according to claim 49 wherein the composition is in the form of a compressed tablet.

83 149. (previously presented) A method according to claim 64 wherein the composition is in the form of a compressed tablet.

84 150. (previously presented) A method according to claim 75 wherein the compressed tablet comprises at least two layers.

C1 cont.

85 151. (previously presented) A method according to claim 78 wherein the compressed tablet comprises at least two layers.

86 152. (previously presented) A method according to claim 81 wherein the compressed tablet comprises at least two layers.

87 153. (previously presented) A method according to claim 77 wherein all of the first release phase is in a first layer and all of the second release phase is in a second layer.

88 154. (previously presented) A method according to claim 78 wherein all of the first release phase is in a first layer and all of the second release phase is in a second layer.

89 155. (previously presented) A method according to claim 79 wherein all of the first release phase is in a first layer and all of the second release phase is in a second layer.



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90. 156. (previously presented) A method according to claim 25 141 wherein the second release phase of the tablet further comprises at least one release retarding excipient which is selected from pH sensitive polymers, release-retarding polymers which exhibit swelling characteristics when in an aqueous environment, polymeric materials which exhibit gelling characteristics when in an aqueous environment, and polymeric materials which exhibit both swelling and gelling characteristics when in an aqueous environment.

91. 157. (previously presented) A method according to claim 90 156 wherein the at least one release retarding gellable polymer is selected from methylcelluloses, carboxymethylcelluloses, low-molecular weight hydroxypropylmethylcelluloses, low-molecular weight polyvinylalcohols, polyoxyethyleneglycols, and noncross-linked polyvinylpyrrolidones.

92. 158. (previously presented) A method according to claim 19 85 wherein the second release phase of the tablet further comprises at least one release retarding excipient which is selected from pH sensitive polymers, release-retarding polymers which exhibit swelling characteristics when in an aqueous environment, polymeric materials which exhibit gelling characteristics when in an aqueous environment, and polymeric materials which exhibit both swelling and gelling characteristics when in an aqueous environment.

C' cont.

93. 159. (previously presented) A method according to claim 27 93 wherein the second release phase of the tablet further comprises at least one release retarding excipient which is selected from pH sensitive polymers, release-retarding polymers which exhibit swelling characteristics when in an aqueous environment, polymeric materials which exhibit gelling characteristics when in an aqueous environment, and polymeric materials which exhibit both swelling and gelling characteristics when in an aqueous environment.

94. 160. (previously presented) A method according to claim 37 103 wherein the second release phase of the tablet further comprises at least one release retarding excipient which is selected from pH sensitive polymers, release-retarding polymers which exhibit swelling characteristics when in an aqueous environment, polymeric materials which exhibit gelling characteristics when in an aqueous environment, and polymeric materials which exhibit both swelling and gelling characteristics when in an aqueous environment.



C

95 161. (previously presented) A method according to claim 90 wherein the at least one release retarding excipient is xanthan gum.

96 162. (previously presented) A method according to claim 92 wherein the at least one release retarding excipient is xanthan gum.

97 163. (previously presented) A method according to claim 93 wherein the at least one release retarding excipient is xanthan gum.

98 164. (previously presented) A method according to claim 94 wherein the at least one release retarding excipient is xanthan gum.

99 165. (previously presented) A method according to claim 95 wherein the xanthan gum is present in an amount from about 0.5% to about 8% by weight of the second release phase.

100 166. (previously presented) A method according to claim 97 wherein the xanthan gum is present in an amount from about 0.5% to about 8% by weight of the second release phase.

C1 cont. 101 167. (previously presented) A method according to claim 95 wherein the xanthan gum is pharmaceutical grade xanthan gum, 200 mesh.

102 168. (previously presented) A method according to claim 97 wherein the xanthan gum is pharmaceutical grade xanthan gum, 200 mesh.

103 169. (previously presented) A method according to claim 99 wherein the xanthan gum is pharmaceutical grade xanthan gum, 200 mesh.

104 170. (currently amended) A method according to claim 1 wherein the pharmaceutically acceptable soluble salt of amoxicillin and the at least one pharmaceutically acceptable organic acid of the second release phase are admixed in intimate contact such that upon exposure to an aqueous environment they interact such that the rate of release of amoxicillin from the solid form of the second release phase is reduced compared to the rate of release of amoxicillin from the solid form of the first release phase.

105 28
~~171~~. (currently amended) A method according to claim ~~94~~ wherein the sodium amoxicillin and the at least one pharmaceutically acceptable organic acid of the second release phase are admixed in intimate contact such that upon exposure to an aqueous environment they interact such that the rate of release of amoxicillin from the solid form of the second release phase is reduced compared to the rate of release of amoxicillin from the solid form of the first release phase.

106 37
~~172~~. (currently amended) A method according to claim ~~103~~ wherein the crystallized sodium amoxicillin and the citric acid anhydrous acid of the second release phase are admixed in intimate contact such that upon exposure to an aqueous environment they interact such that the rate of release of amoxicillin from the solid form of the second release phase is reduced compared to the rate of release of amoxicillin from the solid form of the first release phase.

107 1
~~173~~. (previously presented) A method according to claim ~~13~~ wherein the composition has an in vitro dissolution profile such that about 45% to about 65% of the total amoxicillin is dissolved within 30 minutes, as determined by the <711> Dissolution Test, Apparatus 2, provided in USP 23, 1995, in 900 mL of deionized water, at a paddle speed of 75 rpm.

C 1 cont.

108 37
~~174~~. (previously presented) A method according to claim ~~103~~ wherein the composition has an in vitro dissolution profile such that about 45% to about 65% of the total amoxicillin is dissolved within 30 minutes, as determined by the <711> Dissolution Test, Apparatus 2, provided in USP 23, 1995, in 900 mL of deionized water, at a paddle speed of 75 rpm.

109 1
~~175~~. (previously presented) A method according to claim ~~13~~ wherein the composition has an in vitro dissolution profile such that about 50% to about 75% of the total amoxicillin is dissolved within 60 minutes, as determined by the <711> Dissolution Test, Apparatus 2, provided in USP 23, 1995, in 900 mL of deionized water, at a paddle speed of 75 rpm.

110 1
~~176~~. (previously presented) A method according to claim ~~13~~ wherein the composition has an in vitro dissolution profile such that about 55% to about 85% of the total amoxicillin is dissolved within 120 minutes, as determined by the <711> Dissolution Test, Apparatus 2, provided in USP 23, 1995, in 900 mL of deionized water, at a paddle speed of 75 rpm.



C

111 1
177. (previously presented) A method according to claim ~~13~~ wherein the composition has an in vitro dissolution profile such that about 70% to about 95% of the total amoxicillin is dissolved within 180 minutes, as determined by the <711> Dissolution Test, Apparatus 2, provided in USP 23, 1995, in 900 mL of deionized water, at a paddle speed of 75 rpm.

112 1
178. (previously presented) A method according to claim ~~13~~ wherein the composition has an in vitro dissolution profile such that about 70% to about 100% of the total amoxicillin is dissolved within 240 minutes, as determined by the <711> Dissolution Test, Apparatus 2, provided in USP 23, 1995, in 900 mL of deionized water, at a paddle speed of 75 rpm.

113 56
179. (previously presented) A method according to claim ~~122~~ wherein the composition provides, a mean maximum plasma concentration ($C_{max}$) of amoxicillin of at least 12 ug/mL.

114 56
180. (previously presented) A method according to claim ~~122~~ wherein the composition provides, a mean maximum plasma concentration ($C_{max}$) of amoxicillin of at least 16 ug/mL.

115 56
181. (previously presented) A method according to claim ~~122~~ wherein the composition provides, a mean plasma concentration of amoxicillin of at least 4 ug/mL for at least 4.4 hours.

C 1 cont

116 113
182. (previously presented) A method according to claim ~~179~~ wherein the composition provides, a mean plasma concentration of amoxicillin of at least 4 ug/mL for at least 4.4 hours.

117 56
183. (previously presented) A method according to claim ~~122~~ wherein the composition provides, a mean plasma concentration of amoxicillin of at least 4 ug/mL for at least 4.8 hours.

118 117
184. (previously presented) A method according to claim ~~183~~ wherein the composition provides, a mean maximum plasma concentration ($C_{max}$) of amoxicillin of at least 16 ug/mL.

119 56
185. (currently amended) A method according to claim ~~122~~ wherein the composition provides an area under the curve (AUC) of the total amount of amoxicillin in the composition that is at least 80% of that of the corresponding dosage of amoxicillin taken as a immediate release formulation, over the same dosage period.



C

120 56
186. (currently amended) A method according to claim 122 wherein the composition provides an area under the curve (AUC) of the total amount of amoxicillin in the composition that is at least 90% of that of the corresponding dosage of amoxicillin taken as a immediate release formulation, over the same dosage period.

121 56
187. (currently amended) A method according to claim 122 ~~where~~ wherein the composition provides an area under the curve (AUC) of the total amount of amoxicillin in the composition that is at least 100% of that of the corresponding dosage of amoxicillin taken as a immediate release formulation, over the same dosage period.

122 56
188. (currently amended) A method according to claim 122 ~~where~~ wherein the composition provides an area under the curve (AUC) of the total amount of amoxicillin in the composition that is at least 110% of that of the corresponding dosage of amoxicillin taken as a immediate release formulation, over the same dosage period.

123 56
189. (currently amended) A method according to claim 122 ~~where~~ wherein the composition provides an area under the curve (AUC) of the total amount of amoxicillin in the composition that is at least 120% of that of the corresponding dosage of amoxicillin taken as a immediate release formulation, over the same dosage period.

C1 cont

124 56
190. (currently amended) A method according to claim 122 wherein the composition provides ~~has~~ an AUC, $C_{max}$, and $T_{max}$ substantially according to Figure 5, profile A (Formulation VI).

125 56
191. (currently amended) A method according to claim 122 wherein the composition, provides ~~has~~ an AUC, $C_{max}$, and T>MIC substantially according to Figure 5, profile A (Formulation VI).

126 56
192. (currently amended) A method according to claim 122 wherein the composition provides ~~has~~ an AUC, $C_{max}$, and $T_{max}$ substantially according to Figure 5, profile B (Formulation VII).

127 56
193. (currently amended) A method according to claim 122 wherein the composition provides , ~~has~~ an AUC, $C_{max}$, and T>MIC substantially according to Figure 5, profile B (Formulation VII).

128 194. (currently amended) A method according to claim 1 wherein the ratio of the pharmaceutically acceptable soluble salt of amoxicillin ~~free acid equivalent~~ to the at least one pharmaceutically acceptable organic acid ~~equivalent~~ in the second release phase is about 1:1.

129 195. (currently amended) A method according to claim 5 wherein the ratio of amoxicillin ~~(amoxicillin free acid equivalent)~~ in the first release phase to amoxicillin ~~(amoxicillin free acid equivalent)~~ in the second release phase is about 9:7.

130 196. (currently amended) A method according to claim 128 wherein the ratio of amoxicillin ~~(amoxicillin free acid equivalent)~~ in the first release phase to amoxicillin ~~(amoxicillin free acid equivalent)~~ in the second release phase is about 9:7.

131 197. (previously presented) A method according to claim 20 wherein the citric acid is citric acid anhydrous.

132 198. (previously presented) A method according to claim 23 wherein the pharmaceutically acceptable soluble salt of amoxicillin is crystallized sodium amoxicillin.

C1 cont. 133 199. (currently amended) A method according to claim 56 wherein the amount of amoxicillin ~~(amoxicillin free acid equivalent)~~ administered is at a dosage regimen interval of about 12 hours.

134 200. (previously presented) A method according to claim 1 wherein the composition is administered at a dosage regimen interval of about 12 hours.

135 201. (currently amended) A method according to claim 43 wherein the amount of amoxicillin ~~(amoxicillin free acid equivalent)~~ administered is at a dosage regimen interval of about 12 hours.

136 202. (currently amended) A method according to claim 45 wherein the amount of amoxicillin ~~(amoxicillin free acid equivalent)~~ administered is at a dosage regimen interval of about 12 hours.

137 203. (currently amended) A method according to claim 48 wherein the amount of amoxicillin ~~(amoxicillin free acid equivalent)~~ administered is at a dosage regimen interval of about 12 hours.



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~~204~~. (currently amended) A method for treating a bacterial infection in a patient, the method comprising administering to the patient in need thereof a therapeutically effective amount of a composition in solid dosage form comprising amoxicillin and potassium clavulanate in a weight ratio of amoxicillin to potassium clavulanate from about 2:1 to 20:1, and the amount of amoxicillin is in the range of about 1950 to 2550mg; and the dosage regimen interval is about 12 hours,

such that the amount of amoxicillin released over thirty minutes is in the range about 45 to about 65% of the total amoxicillin content, over sixty minutes is in the range about 50 to about 75% of the total amoxicillin content, over two hours is in the range about 55 % to about 85% of the total amoxicillin content, over 180 minutes is in the range about 70 % to 95% of the total amoxicillin content and over 240 minutes is in the range about 70 to about 100% of the total amoxicillin content, as tested by the USP Dissolution Test, Apparatus 2, method at 37 degrees C, a paddle speed of 75 rpm and in 900 ml deionized water, over a period of 8 hours;

~~chosen such that the~~ and which provides a mean maximum plasma concentration (Cmax) ~~is~~ of at least 12 micrograms/ml and ~~the~~ a mean time that the plasma concentration exceeds 4 micrograms/ml ~~is~~ for at least 4.4 hours, when tested in a group of at least 7 healthy humans, based on blood sampling at half hourly intervals for the first two hours and thereafter at hourly intervals ~~(at the start of a light meal and after an overnight fast)~~.

C 1 cont.

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~~205~~. (currently amended) A method for treating a bacterial infection in a patient, the method comprising

administering to the patient in need thereof a composition in solid dosage form comprising amoxicillin and potassium clavulanate, such that the amount of amoxicillin is about 2000mg and comprising a first release phase and a second release phase;
the first release phase comprising potassium clavulanate and a first portion of the amoxicillin;
the second release phase comprising a second portion of amoxicillin, which is a pharmaceutically acceptable soluble salt of amoxicillin, and at least one pharmaceutically acceptable organic acid which are admixed in intimate contact at a ratio of from 20:1 to 1:2 ~~(amoxicillin free acid equivalent to organic acid equivalent)~~; such that the weight ratio of amoxicillin to potassium clavulanate is from 2:1 to 20:1, and the solid dosage is administered at a regimen interval of about 12 hours,

and wherein the solid dosage is such that the amount of amoxicillin released over thirty minutes is in the range about 45 to about 65% of the total amoxicillin content, over sixty minutes is in the range about 50 to about 75% of the total amoxicillin content, over two hours is in the range about 55 % to about 85% of the total amoxicillin content, over 180 minutes is in the range



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about 70 % to 95% of the total amoxicillin content and over 240 minutes is in the range about 70 to about 100% of the total amoxicillin content, as tested by the USP Dissolution Test, Apparatus 2, method at 37 degrees C, a paddle speed of 75 rpm and in 900 ml deionized water, over a period of 8 hours;

~~chosen such that the~~ and which provides a mean maximum plasma concentration (Cmax) ~~is~~ of at least 12 micrograms/ml and ~~the~~ a mean time that the plasma concentration exceeds 4 micrograms/ml ~~is~~ for at least 4.4 hours, when tested in a group of at least 7 healthy humans, based on blood sampling at half hourly intervals for the first two hours and thereafter at hourly intervals~~, (at the start of a light meal and after an overnight fast)~~.

140 2
~~206~~. (new) A method according to claim ~~18~~ wherein the bacterial infection is a respiratory tract infection.

141 140
~~207~~. (new) A method according to claim ~~206~~ wherein the respiratory tract infection is community acquired pneumoniae (CAP), acute exacerbation of chronic bronchitis (AECB), or acute bacterial sinusitis (ABS).

C 1 cont.

142 141
~~208~~. (new) A method according to claim ~~207~~ wherein the composition is administered over 7 to 14 days.

143 138
~~209~~. (new) A method according to claim ~~204~~ in which the bacterial infection is caused by at least one of the organisms *S. pneumoniae, H. influenzae,* and *M. catarrhalis.*

144 143
~~210~~. (new) A method according to claim ~~209~~ wherein the *S. pneumoniae* are Drug Resistant *S. pneumoniae* and Penicillin Resistant *S. pneumoniae* organisms.

145 143
~~211~~. (new) A method according to claim ~~209~~ wherein the bacterial infection is a respiratory tract infection.

146 145
~~212~~. (new) A method according to claim ~~211~~ wherein the respiratory tract infection is community acquired pneumoniae (CAP), acute exacerbation of chronic bronchitis (AECB), or acute bacterial sinusitis (ABS).



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147 213. (new) A method according to claim 212 wherein the composition is administered over 7 to 14 days.

148 214. (new) A method according to claim 205 in which the bacterial infection is caused by at least one of the organisms *S. pneumoniae, H. influenzae,* and *M. catarrhalis.*

149 215. (new) A method according to claim 214 wherein the *S. pneumoniae* are Drug Resistant *S. pneumoniae* and Penicillin Resistant *S. pneumoniae* organisms.

C' cancel. 150 216. (new) A method according to claim 214 wherein the bacterial infection is a respiratory tract infection.

151 217. (new) A method according to claim 216 wherein the respiratory tract infection is community acquired pneumoniae (CAP), acute exacerbation of chronic bronchitis (AECB), or acute bacterial sinusitis (ABS).

152 218. (new) A method according to claim 217 wherein the composition is administered over 7 to 14 days.